

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10
(fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

PLAINTIFF TRUTEK CORP'S RESPONSE TO DEFENDANT
BLUEWILLOW BIOLOGIC'S MOTION TO EXCLUDE EXPERT
REPORT AND TESTIMONY OF AMIRALI Y. HAIDRI

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I. INTRODUCTION

This brief is a response to "Defendant/Counter Plaintiff BlueWillow Biologics, Inc.'s Motion to Exclude the Expert Report and Testimony of Amirali Y. Haidri," submitted as ECF 56 on March 15, 2023. On March 30, 2023, the Court ordered that the time for replying to motions to exclude expert witness testimony is to be extended by two weeks. Subsequently, on April 21, 2023, the Court ordered that Plaintiff's response to Defendants motions to exclude will be due by May 22, 2023.

In its motion document, Defendant/Counter Plaintiff BlueWillow Biologics, Inc. ("Defendant" or "BlueWillow"), moved the Court to "exclude the expert report and testimony" of Amirali Y. Haidri ("Haidri" or "Mr. Haidri"). Mr. Haidri was designated by Plaintiff, Trutek Corp. ("Plaintiff" or "Trutek"), as its expert to offer rebuttal testimony to BlueWillow's expert, Mansoor M. Amiji ("Amiji" or "Dr. Amiji"). The reasons given by BlueWillow for excluding Mr. Haidri's testimony are three-fold (ECF 56, pg. 2/35, ¶3):

1. "his report consists entirely of inadmissible legal arguments."
2. "Haidri is facially unqualified to provide technical expert testimony regarding the pertinent art, alleged invention, or accused product."

3. "Haidri's opinions lack reference to a verifiable or testable methodology, let alone a sufficiently reliable methodology under *Daubert*.¹"

Plaintiff denies all three statements *supra* alleged by Defendant in its motion.

On June 27, 2022, Amiji submitted his expert report, which asserted that U.S. Patent 8,163,802 ("the '802 Patent"), owned by Trutek, is invalid under 35 U.S.C. §§ 101, 102, 103, and 112. Amiji's report was uploaded by Defendant as ECF 56-2. In response, on August 15, 2022, Mr. Haidri submitted his expert report with rebuttal opinions of those expressed by Amiji. Haidri's report was uploaded by Defendant as ECF 56-3.

Amiji is BlueWillow's only expert. Dr. Amiji submitted expert reports on patent invalidity, non-infringement, and claim construction. On March 29, 2023, Plaintiff moved to exclude Amiji's testimony specifically with regard to his opinions on invalidity of the '802 Patent (ECF 61). The Amiji report on invalidity consists entirely of legal opinions. Despite his other qualifications as an expert witness, Amiji is not an attorney. He was informed of the law by counsel. He did not perform his own search for prior art documents, but was instead provided with them by counsel. Moreover,

¹ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

the opinions stated in his report show a lack of understanding of both the patent law and the facts used by him to support his conclusions.

II. ARGUMENT

A. LEGAL STANDARD

Fed. R. Evid 702 states that, "a witness, who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise ..." In a case cited by Defendant in its legal brief,² *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2009), the Federal Circuit reversed a decision by the District Court in the Eastern District of Michigan³ that allowed a "patent attorney who lacked appropriate technical qualifications [to] testify as [an] expert witness on how [the] disclosed invention accused system, and prior art operated, or [to] offer his opinion as to noninfringement and invalidity." However, the reason for excluding the witness' testimony was based solely on his not being qualified as an expert in the underlying technology relating to the asserted patent. The Federal Circuit held that an experienced patent attorney may "testify as to

² Defendant's Brief in Support of its Motion to Exclude Report and Testimony of Amirali Y. Haidri, at Pages 12, 16, 17, 19, and 20.

³ 485 F.Supp.2d 805.

patent office procedure generally ... [and] on general procedures involved in the patent application process." *Id.* at 1361.⁴

Thus, the following issues arise with regard to Mr. Haidri's proffered testimony as an expert witness:

1. what is the underlying technology of the asserted patent;
2. to what areas of relevant expert testimony are Mr. Haidri's opinions directed; and
3. what are Mr. Haidri's qualifications to provide expert testimony.

1. **The underlying technology of the asserted patent is organic chemistry rather than pharmaceutical science.**

On page 3 of its brief in support of its motion to exclude Mr. Haidri's expert report and testimony, the Defendant stated:

*Without a stretch of the imagination, one would expect that a **technical** expert in a case related to the alleged invention and accused product would have relevant technical experience in **at least** one or more of the following to be seriously considered as a qualified expert in this matter: (1) electrostatics, (2) pharmaceutical formulation and product development, (3) medicine, (4) infectious diseases, (5) topical drug application, (6) cationic agents, or (7) biocidal agents.*

⁴ Citing *Bausch & Lomb, Inc. v. Alcon Laboratories, Inc.*, 79 F.Supp.2d 252, 254-55 (W.D.N.Y. 2000).

Here, the Defendant's statement of proposed qualifications for a technical expert is based on an incorrect assumption of the field of the invention of the '802 Patent and its underlying technology. The '802 Patent does not disclose a pharmaceutical product nor does it encompass medical technology.

The preamble of independent claim 1 of the '802 Patent reads, "[a] method for electrostatically **inhibiting** harmful particulate matter from infecting an individual through nasal inhalation ...," and the preamble of independent claim 2 reads, "[a] formulation for electrostatically **inhibiting** harmful particulate matter from infecting an individual through nasal inhalation"⁵ Claims 1 and 2, as originally submitted in the patent application⁶ used the word, "preventing," which was amended to read, "inhibiting" after the first USPTO office action. That office action is attached hereto as Exhibit 1.

In said office action, the examiner rejected the claims under 35 U.S.C. § 112 First Paragraph, stating that:

the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host ... may be prevented, ... i.e., a material is ever kept from introduction into the system of a host, is doubted because ... while an effective prevention against the

⁵ Emphasis added.

⁶ U.S. Patent Application No. 12/467,271 filed May 16, 2009.

introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host. (Id. Page 3.)

The examiner continued:

As indicated above, the term "preventing" is here being interpreted as being synonymous with a circumstance such as where a vaccine is administered against a pathogen and the host to whom such was administered does not suffer from the pathogen's effect even when present in the host's system. As such the term "preventing" circumscribes a circumstance of almost absolute success. Because such success is not reasonably possible with the treatment of most infectious diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as encompassed by the present claims, the specification, which lacks an objective showing where prevention is actually manifest, is viewed as lacking an enabling disclosure of the same. (Id. Page 4.)

Finally, the examiner indicated how the Applicant might overcome the rejection:

In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims. (Id. Page 2.)

In its reply to this office action, the Applicant amended claims 1, 2, and 8, by following the examiner's suggestion, and replacing the word "preventing" with "inhibiting." This amendment was now binding upon the

Applicant in defining his invention under the doctrine of prosecution history estoppel.

The formulation disclosed in the '802 Patent is not a pharmaceutical product, nor does the method of use depend on pharmaceutical science. The effect of the disclosed formulation on the user does not occur inside the body. Because the formulation inhibits infection by preventing some harmful particles from entering an individual's respiratory system, its effects all occur outside the body. The harmful particles that circumvent the electrostatic protection of the formulation and enter the respiratory system can still infect the individual. Instead, the formulation protects the user from inhaling the particles by electrostatically capturing them in the vicinity of his nostrils. The formulation is viscous and sticky, and it holds the particles in place so as not to be inhaled into the respiratory system. For those that are inhaled, most of them are rendered harmless by a biocide contained in the formulation. Therefore, the object of the invention is to inhibit some or most of the harmful particles from being inhaled. The '802 Patent does not disclose a pharmaceutical formulation. The compound's function is analogous to a face mask that traps harmful particles before they are inhaled.

In his opening report (ECF 56-2), Plaintiff's expert, Amiji, admits, "I understand that Trutek's products are considered cosmetics given that they

did not go through the Federal Drug Administration drug approval process."

Nonetheless, the formulation is a compound that consists of a number of organic chemicals. Their functions can be understood by an organic chemist or a pharmacist.

The asserted qualifications proposed by Defendant⁷ *supra* are incorrect for an expert in the field of the invention for the '802 Patent. The correct field of the invention is organic chemistry. Even Ashok Wahi, the inventor of the formulations of the '802 Patent did not possess most of Defendant's proposed technical skills. From the expert qualifications proposed by Defendant⁷, expertise in pharmaceutical formulation, medicine, infectious diseases, and topical drug application are irrelevant and unnecessary for a witness to assist the trier of fact. The formulation is not a drug – it is a chemical compound. Instead, an expert witness should at least have expertise in organic chemistry and formulation of organic compounds. He should be familiar with the functions of cationic agents and biocides. Electrostatics is a subject taught in high school physics as well as in undergraduate physics courses required for all science majors. An organic chemist or a pharmacist would be familiar with these subjects.

⁷ (1) electrostatics, (2) pharmaceutical formulation and product development, (3) medicine, (4) infectious diseases, (5) topical drug application, (6) cationic agents, or (7) biocidal agents.

2. **Mr. Haidri intends to proffer opinions on subjects in which he is well qualified.**

Mr. Haidri was engaged as a rebuttal expert to opinions expressed by Defendant's expert, Dr. Mansoor Amiji. He intends to offer opinions on the subjects of (1) the chemistry, chemical properties, and physical properties of the formulations of the '802 Patent as well as those of the cited prior art; (2) patent office procedure generally and general procedures involved in the patent application process; (3) a person having ordinary skill in the art; (4) the issues of patentable subject matter, written description, and enablement of the '802 Patent; (5) the issues of anticipation and obviousness of the claims of the '802 Patent; (6) rebuttal of Dr. Amiji's opinions on invalidity of the '802 Patent; and (7) rebuttal of Dr. Amiji's opinions where he incorrectly opines on patent law.

In *Berry v. City of Detroit*, 25 F.3d 1342 (6th Cir. 1984), the Sixth Circuit held that "while experts may be qualified 'to assist the trier of fact,' [they are] not qualified to compete with the judge in the function instructing the jury." *Id.* at 1354. "In condemning this line of testimony, the court stated: 'This circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion.'" *Id.*

Other than to rebut incorrect legal opinions proffered by Amiji, Mr. Haidri has no intention of stating legal opinions or offering legal

conclusions. Yet, he will cite USPTO practice and procedure to support his testimony. However, Mr. Haidri did cite case law in his expert report on patent validity (ECF 56-3). An expert report is not admitted into evidence. It may be used by the witness to refresh his memory or it may be used by adversary counsel to impeach his testimony. But, it is not testimony in itself. It was not submitted under oath. Yet, an expert report must not only provide the expert's opinions, but also the basis for his opinions. Its purpose is to inform the adverse party of his opinions. His case citations were included to inform adversary counsel of the legal basis in addition to the factual basis for his opinions. They were presented in his report to show where Amiji misinterpreted the law. However, Mr. Haidri will not offer legal testimony at trial.

Dr. Amiji's expert report consisted largely of legal opinions. Mr. Haidri concluded that Dr. Amiji was either misinformed or did not understand the law. Defendant states that Mr. Haidri's expert report consists entirely of legal opinions. This is not true. Mr. Haidri included case law in his report to demonstrate to adversary counsel the bases for his opinions that pointed out the errors in Dr. Amiji's stated legal opinions. Where Dr. Amiji proffers an opinion that forms a legal conclusion, the Plaintiff has no choice but to rebut that opinion to the trier of fact. However, that rebuttal will be

based on Patent Office procedure and standards, which are included in his report. But, if no such opinion is offered by Dr. Amiji, Mr. Haidri will not provide rebuttal.

Regarding reliance on USPTO practice and procedure with respect to patent application prosecution, the basic reference is the Manual of Patent Examining Procedure ("MPEP"). In the case of *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002), the Court held: "The Guidelines, like the Manual of Patent Examining Procedure ('MPEP'), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute"⁸ The MPEP forms the basis of USPTO practice and procedure in both patent prosecution and attacks on patent validity at the Patent Trials and Appeals Board ("PTAB").

B. Mr. Haidri is qualified to testify in this matter because of his scientific and technical education and background as well as his understanding of patent law and procedures of the United States Patent and Trademark Office ("USPTO").

1. Mr. Haidri is both an organic chemist and a patent attorney. His education in chemical engineering and chemistry, his legal education, his practice before the USPTO, and his employment experience qualify him to testify in this matter.

⁸ Citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n 10 (Fed Cir. 1995).

Mr. Haidri's technical qualifications represent a threshold issue. Therefore his qualifications as an expert in the pertinent art will be addressed first. His resume is submitted herewith as Exhibit 2.

During the summers of 1967-1968, Mr. Haidri was employed by Quantum, Inc. in Wallingford, Connecticut performing research and development in polymer chemistry. There, he worked in a laboratory preparing experimental formulations. During the academic year 1968-1969, he was an employee of the University of Leeds as a laboratory demonstrator for undergraduates in the Physics Department. He attended the University of Leeds in England as an undergraduate, and he earned his B.S. degree in chemical engineering with honors in 1971. Afterwards, he was employed by W.P. Thompson & Co. in Liverpool until 1972 as a technical associate.

Returning to the United States, Mr. Haidri was employed by Hazeltine and Lake in New York as an associate and Director of the Trademark Department from 1972 until 1981. During this period, he attended New York Law School, and he was graduated *cum laude* with a J.D. in 1980. He is currently licensed to practice law in New York and New Jersey. Mr. Haidri also sat for and passed the USPTO patent registration examination (a.k.a. the patent bar exam). He became licensed to practice in patent matters before the USPTO in 1978.

From 1981 until 1983, Mr. Haidri worked for Texaco Development Corporation in White Plains, New York prosecuting patents involving chemical technology. During this period, he began graduate studies at New York University, and he earned his M.S. degree in organic chemistry in 1983. All this time, he attended courses and had hands-on laboratory experience in disciplines such as analytical chemistry, biochemistry, stereochemistry, and nuclear magnetic resonance imaging. His thesis was titled, "Transition Metal Catalyzed Synthesis Gas Homologation of Carboxylic Acids."

Mr. Haidri is not a pharmacist. While it is true that Mr. Haidri neither created nor tested pharmaceutical formulations (*i.e.*, drugs), contrary to assertions by Defendant, he has much experience in the laboratory in formulating a wide variety of organic and inorganic compounds.

From 1983 until 1984, Mr. Haidri was employed as a patent attorney by Lever Brothers Company in Edgewater, New Jersey. This was the location of their research and development laboratories. There, he worked closely alongside chemists in the laboratory in their efforts to patent their inventions. He was involved with inventions of soaps, fragrances, foods, and over-the-counter pain relievers. These inventions were eventually marketed by Lever Brothers under the brand names of Aunt Jemima,

SHEDDS, and Aunt Millie. He worked with the chemist who developed the Dove Beauty Bar. During this period, he wrote the entire specifications for these chemical products that included chemical formulations to relieve pain and inflammation. Overall, the vast majority of patents filed and prosecuted by Mr. Haidri over the years have been in the field of organic chemistry. Mr. Haidri is still actively involved as a patent attorney.

After 1984, Mr. Haidri devoted his time to developing a successful law practice. In September 2019, he filed a lawsuit on behalf of Trutek Corp. against Matrixx Initiatives, Inc. for infringement of the '802 Patent by their ZICAM[®] brand over-the-counter nasally administered cold remedies.⁹ The matter was settled in November 2020. During this period, Mr. Haidri gained intimate familiarity with the technology of the '802 Patent. He was already familiar with the functionality of cationic and biocidal agents as well as of surfactants, adhesives, and thickeners. Based on his background in chemistry and physics, he understands and is intimately familiar with the concepts of electrostatic attraction and repulsion, and of adjusting viscosity, adhesion, and cohesion of a chemical formulation.

It should be noted that the USPTO has strict requirements for even allowing an applicant to sit for the patent bar exam. An applicant must have

⁹ *Trutek Corp. v. Matrixx Initiatives, Inc.*, 3:19-cv-17647 (D. N.J.)

a university education in at least one of USPTO's approved scientific disciplines. Mr. Haidri's approved qualification stemmed from his education in chemistry and chemical engineering. Although the USPTO has an organization where patent trials and appeals are conducted, most of the work of a patent practitioner involves preparing patent applications and prosecuting those applications to secure a patent. This requires a thorough understanding of patent law and the technology of the invention to be patented. Most of the work in preparing a patent application is technical. Mr. Haidri was involved almost entirely in the preparation of patent applications for chemical products. Without his knowledge of chemistry, he would have been unable to develop the patents for his employers. A patent attorney who prepares chemical patents is not just a lawyer. He must also be a knowledgeable chemist.

2. Mr. Haidri has expertise in the technology of the '802 Patent, and is qualified to provide testimony regarding said technology.

Referring to the ¶28 in Amiji's Report (ECF 56-2), Dr. Amiji classifies the formulations disclosed in the '802 Patent as cosmetics rather than pharmaceuticals. Trutek agrees with this designation. The disclosed formulations of the '802 Patent inhibit infection of a person due to nasal inhalation of harmful particles (such as bacteria, viruses, *etc.*) by capturing

at least some of the particles, holding them in place, and inactivating them using a biocide. The effect of applying the formulations does not occur inside the body. They are not vaccines. Thus, they are not pharmaceuticals.

The '802 Patent's formulations include ingredients such as (1) a quaternary thickener, (2) a preservative, (3) a conditioner, (4) an emulsifier, (5) a biocidal agent, (6) a neutralizing agent, (7) a surfactant, (8) a thickener, (9) an emollient, (10) a humectant, and (11) a binder. ('802 Patent, 4:65-5:13.) Mr. Haidri is familiar with all of these types of ingredients, as are most organic chemists. Further, he understands the functions of all of the ingredients named in the example formulations, and especially the quaternary ammonium compounds as well as benzalkonium chloride. He has knowledge of cationic agents and their abilities to create a positively charged electrostatic field. Familiarity with the technology of the '802 Patent does not require an expert who is a registered pharmacist.

Although, the Court disagrees with Amiji's proposed qualifications of a person having ordinary skill in the art, even Amiji proffers that such a person would have "an M.S. degree in chemical engineering, pharmaceutical science, or a related field (or the equivalent)." (ECF 56-2, pg. 33/116, ¶68.) Mr. Haidri has a B.S. degree in chemical engineering and an M.S. degree in organic chemistry. Moreover, having hands-on experience in formulating

pharmaceuticals should not be required for a qualified expert to opine on the formulations disclosed and claimed in the '802 Patent. Nor is the technology so complex that only a microbiologist would understand it. Any organic chemist would understand how these formulations are prepared and what experimentation is required to adjust the concentrations of the ingredients to obtain a desired effect. Further, Mr. Haidri has a particular familiarity with the '802 Patent based upon his work regarding that patent for the past five years. Thus, Mr. Haidri has the qualifications of a skilled professional who is able to explain the technology of the '802 Patent to the fact finder.

3. Mr. Haidri's experience in prosecuting patents for many years qualifies him to provide testimony on the prior art patent references cited by BlueWillow.

A patent is a complex legal document. It consists of two parts – the inventor's disclosure of the invention and the protection afforded to the inventor as *quid pro quo* for his disclosure. The inventor's disclosure of the invention is contained in the patent's specification and drawings. The protection afforded to the inventor is contained in the claims. While a specification is generally understood by persons having ordinary skill in the art, most lay people have difficulty understanding the language and scope of the claims. A claim must be written as a single sentence. Generally, it is a run-on sentence, where the only syntax requirements are that the claim must

begin with a capital letter and end with a period and that the claim cannot consist of multiple sentences. There have been instances where claims are single sentences that span several pages.

Invalidity of patent claims based on prior art challenges fall into two categories – anticipation (based on 35 U.S.C. § 102) and obviousness (based on 35 U.S.C. § 103). If a claim is anticipated by the prior art or is obvious over the prior art, it is invalid. Every patent practitioner must be completely familiar with the standards for anticipation and obviousness.

In his report, Amiji stated that the asserted claims of the '802 Patent were invalid based on anticipation and obviousness over the prior art. Mr. Haidri provided detailed explanations showing not only that Amiji was wrong, but also that he used incorrect standards and procedures to prove invalidity of the claims.

For a claim to be anticipated, a single prior art reference must teach every element of the claim. Someone else must have invented the exact same thing. If the prior art reference is silent about even one claimed element, the claim is not invalid for anticipation.

On the other hand, obviousness of a claim may be shown by combining two or more prior art references. That combination is performed by a person having ordinary skill in the art who would be motivated to

combine the references at the time that the inventor made his invention. However, the combination of the references must also teach every element of the claim. IF the combination of references is silent about even one claimed element, the claim is not invalid for obviousness.

The person having ordinary skill in the art is a fictitious person who is not a genius or an inventor. He or she is a technician. But, he or she is not an automaton either. That person is presumed to have intimate knowledge of all relevant prior art. In addition, the person of ordinary skill can only have had the motivation to combine the references at the time the invention was made.

Patent attorneys as well as patent examiners are experts in selection of the person having ordinary skill in the relevant art. This expertise is essential in patent prosecution.

It is essential to choose this fictitious person carefully, lest he or she be chosen to have extraordinary skill in the art. A person having extraordinary skill in the art would have the insight to combine references, where a person having ordinary skill would lack that insight. Incorrect choice of this person of ordinary skill could lead to reversible error if it influences the ultimate conclusion on obviousness. *Custom Accessories*,

Inc. v. Jeffrey-Allen Indus., Inc., 807 F.2d 955 (Fed. Cir. 1986)¹⁰ In his report (ECF 56-3, pages 24-28), Mr. Haidri discusses and opines regarding the selection of this person having ordinary skill in the art. His opinions are virtually identical to the opinions of Dr. Edward Lemmo, one of Plaintiff's other experts. Their opinions differ from those of Defendant's expert, Dr. Amiji. Amiji described a person having extraordinary skill. In his deposition taken October 14, 2022, Dr. Amiji described himself as a person of ordinary skill in the art (ECF 61-3, page 82, lines 2-5). In its decision on claim construction, this Court adopted Plaintiff's interpretation of the person of ordinary skill in the art. ECF 53. Thus, Dr. Amiji viewed the issue of invalidity of the claims through the wrong lens. He used the wrong person of ordinary skill.

In his report (ECF 56-3, pages 29-38), Mr. Haidri discusses the specification and asserted claims of the '802 Patent in detail. Then, on pages 52-76, Mr. Haidri rebuts all of the allegations of invalidity based on anticipation and obviousness over the prior art references proffered by Amiji in detail. As a patent attorney, Mr. Haidri knows that patents are presumed valid, and that the burden of proof of invalidity is on the Defendant under a clear and convincing standard. *Microsoft Corp. v. i4i Ltd. Partnership*, 564

¹⁰ See also *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565 (Fed. Cir. 1986).

U.S. 91 (2011). See also 35 U.S.C. § 282. In Mr. Haidri's report (pages 39-76), in section headings (E-G), he opines that, "the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid ...". It is Plaintiff's position that if Amiji is permitted to opine on anticipation or obviousness, Plaintiff needs to show that the clear and convincing standard was not met. As argued *supra*, Mr. Haidri's expert report will never be admitted into evidence. Yet, whether he uses the words, "clear and convincing" in testimony is a determination to be made by the court prior to trial. However, the reasoning presented on pages 52-76 is valid independent of the section heading wordings. Plaintiff will still need to show that Defendant failed to meet its burden to show invalidity by clear and convincing evidence. This must be demonstrated point-by-point, and it is far too burdensome and confusing for the fact finder if Plaintiff is allowed only to do this in closing arguments. This must be shown by expert testimony.

C. Defendant's Assertions Under *Daubert* Fail to Provide Proper Basis or Applicability.

On pages 21-25 of its brief, Defendant made the following statements:

- (1) "Haidri's methodology is not objectively or independently verifiable."
- (2) "Haidri relied on flawed legal standards and factual predicates."

Regarding Statement (1), Defendant fails to state what methodology is required for Mr. Haidri's rebuttal testimony or how it is to be verified. Mr.

Haidri intends to use his understanding of the '802 Patent's technology as well as his knowledge of USPTO practice and procedure to show deficiencies in Dr. Amiji's opinions.

Regarding Statement (2), Mr. Haidri's reliance on patent statutes as well as USPTO practice and procedure was not flawed. Instead, he pointed out that Amiji presented legal opinions in his report which were wrong and which Amiji was not qualified to present. Dr. Amiji admitted that he is not an attorney and that he was informed of the law by counsel. Mr. Haidri opined that Dr. Amiji misunderstood the law and that he did not use the proper analysis to prove patent invalidity. Plaintiff disagrees with Defendant's allegations that his factual predicates were wrong. There is clearly a difference of opinion between the two experts, but that does not create sufficient reason for disqualification of Plaintiff's expert. It must be noted that Mr. Haidri intends only to rebut testimony of Defendant's expert.

D. Regarding Plaintiff's Pending Motions Submitted Concurrently

There are two motions currently pending motions by Plaintiff that bear on Defendant's present motion:

ECF 61: **Plaintiff's Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D.; and**

ECR 62: **Motion For Partial Summary Judgment Declaring That U.S. Patent No. 8,163,802 is Valid.**

If either of these two motions are granted by the Court, much of Mr. Haidri's testimony will become unnecessary. Dr. Amiji is Defendant's only expert on the issue of invalidity of the '802 Patent. The '802 Patent is presumed valid under 35 U.S.C. § 282(a). While this presumption is rebuttable, it is the Defendant's burden to prove invalidity of the claims at issue by a clear and convincing evidentiary standard.

III. CONCLUSION

In its presentation *supra*, Plaintiff made the following arguments:

1. The underlying technology of the '802 Patent is organic chemistry rather than pharmaceutical science. The formulations disclosed in the '802 Patent are not drugs. They function only outside the body and act as a filter for harmful particles much like a face mask. Either an organic chemist or a pharmacist is able to opine on the formulations and their efficacy.
2. Mr. Haidri is engaged only as a rebuttal witness to Dr. Amiji's opinions. He intends to offer opinion testimony regarding the validity of the '802 Patent. As a basis for his opinions he will use his knowledge of organic chemistry, his understanding of the '802 Patent based on his experience therewith, and his knowledge of USPTO practice and procedure. He will only rebut using legal conclusions if

the Court allows Dr. Amiji to present his own legal conclusions.

However, Mr. Haidri intends to show that Defendant fails to prove invalidity of the '802 Patent by a clear and convincing standard.

3. Mr. Haidri is qualified to testify based on his background, education, and experience as an organic chemist in addition to his qualifications as a patent attorney. This satisfies the conditions set forth in *Sundance* for allowing this type of testimony.
4. Mr. Haidri's rebuttal expert report on patent validity shall not be admitted into evidence at trial. It only serves two purposes. First, it may be used by Mr. Haidri to refresh his recollection while testifying. Second, it may be used to impeach Mr. Haidri's testimony. Therefore, Defendant's motion to exclude Mr. Haidri's expert report is improper.

Based on the arguments submitted *supra*, Plaintiff respectfully requests this Court to deny Defendant's Motion to Exclude the Expert Report and Testimony of Amirali Y. Haidri.

Dated: May 11, 2023

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10
(fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

CERTIFICATE OF SERVICE

Undersigned hereby states that on May 22, 2023, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.



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